Claims 1 and 159-182 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lai '461 or Lai '717 or Valint or Mueller each in view of Hofer or Lin or Sugiyama or Kiguchi. Applicants' claims are directed to lens of a particular polymer composition, which has been subjected to a surface treatment. The Lai patents, Valint, and Mueller all disclose applicants' recited lens having the required polymer material of fluorine monomers and comonomers. The difference between the claims and the Lai patents, Valint, and Mueller is that the references do not recite surface treatment. Hofer, Lin, Sugiyama and Kiguchi all disclose surface treatment of lens. See the Abstract and claim 1 of Hofer, Lin, Sugiyama, and Kiguchi. It would be obvious to one of ordinary skill in the art to subject the lens of the Lai patents, Valint, or Mueller to the surface treatment of Hofer, Sugiyama, Kiguchi, or Lin. The motivation is that it would be desirable to one of ordinary skill in the art to improve the lens of the primary references by the surface treatment methods of Hofer, Lin, Sugiyama, or Kiguchi. PP. 2-3, Office Action.

Applicants traverse the Office Action for the following reasons, as it would not be obvious to one combine the above primary references with any of the secondary references. To the contrary, there is no motivation to one of skill in the art to combine the references. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there **is some teaching, suggestion, or motivation to do** so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See, In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also MPEP 2143.01.

It should be recognized that the fact that the prior art could be modified so as to result in the combination defined by the claims at bar would not have made the modification obvious unless the prior art suggests the desirability of the modification. See, In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986). Recognizing, after the fact, that such a modification would provide an improvement or advantage, without suggestion thereof by the prior art, rather than dictating a conclusion of obviousness, is an indication of improper application of hindsight considerations. Simplicity and hindsight are not proper criteria for resolving obviousness. See, In re Warner, 379 F.2d 1011, 154, USPQ 173 (CCPA 1967).

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Turning first to the primary references, Lai U.S. Patent No. 5,034,461 (" '461 Patent) deals with urethanes useful in biomedical applications. The disclosure reads about domains of hard and soft segments, which are typical for urethane chemistries Domains are regions of the polymer that segregate, but they can both be hydrophilic and/or hydrophobic. In this regard, attached for the Examiner's consideration is a response to the Reexamination Control No. 90/005,283, addressing U.S. Patent No. 5,760,100, which by way of example, sets forth the deficiencies of the invention of the Lai '461 Patent for use as a contact lens material. Attachment.

Lai U.S. Patent 5,158,717 (" ' 717 Patent) deals with Barex™ mold material. In the '717 Patent, it is asserted that by using this mold material, with a monomer mixture with hydrophilic monomers contained therein, the molds will render the resultant article (contact lens) more hydrophilic than if you did not use the material. The hydrophilic monomer is said to "bloom" to the surface due to the polar nature of the mold material. The Lai '717 Patent equates this asserted hydrophilicity to ocular compatibility without any data. The preparation of contact lenses appears to not have been addressed, as the '717 patent does not autoclave the article. In the Lai '717 Patent, the article is extracted and then equilibrated in water. This patent does not consider the surface mobility of siloxane materials and their inherent ability to rotate about the backbone; thus becoming hydrophobic with time.

U.S. Patent No. 5,219, 965 (" '965 Patent") to Valint et al. discloses monoliths and a way of manufacturing monolith contact lenses or medical polymers. The surface modification that is mentioned is accomplished by hydrolyzing the wetting agents into highly polar amino acids (Column 13, lines 44-57). Also see Summary of the Invention. See also, Column 12, line 41). While the Abstract mentions surface modification, yet it does not appear to be fully described in the patent. What the '965 Patent appears to disclose is that the polymerizible surfactants render the material sufficiently compatible as a monolith. Further, in Column 3, the '965 Patent describes that DMA is one of the polymerizible surfactants that may be used.

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U.S. Patent No. 5,334,681 (" '965 Patent) to Mueller et al. discloses the usage of fluoro compounds in contact lenses, and is limited to the usage of fluoro-acrylates. Also, this patent fails to consider the structural necessities of surface treatment, as well as ocular compatibility.

Based upon this review of the primary references and as stated by the Examiner, none of the primary references disclose or describe any effective surface treatment. Turning now to the secondary references, each lacks sufficient motivation to one of ordinary skill in the art to conduct the surface treatment, as presently claimed. U.S. Patent No. 4,214,014 (" ' 014 Patent) to Hofer et al. describes surface modification for contact lenses, which uses a setup that actually sputters the surface of the contact lens away, cleaning the surface and oxidizing it. Also, the oxidation is transient and the material will not remain highly wetting after autoclaving. Also, the metallic electrodes sputter metal on the lens surface; which will eventually discolor the lens. Like the JP reference addressed by Dr. Lynn Winterton in declaration in the reexamination of U.S. Patent No. 5, 760,100, a patent based upon a parent of the present application, this type of surface treatment is inadequate, due to polymer mobility and the natural tendency of a polymer to reorient its surface to accommodate a given environment to which it is exposed. See, para. 50 to 75, Winterton Declaration, Attached.

U.S. Patent No. 4,687,816 (" '816 Patent) discloses a treatment of a specific type of soft lens with a very specific acid anhydride while the lens is swollen. The rational is to strengthen the lens and prevent surface contamination. While biocompatibility may the objective, the type of treatment is very specific in type and nature to specific hydogels cannot be fairly be extended to other type of lens. See also, L. Winterton Declaration.

U.S. Patent No. 4,980,208 (" ' 208") describes a methodology for use with hard lenses. It describes a specific treatment of lenses made from silicone methacrylates and fluoro-acrylates. These are hard lenses, not soft lenses. One of ordinary skill in the art would not extend the use and manufacture of hard lenses to soft lenses. This can be illustrated by the fact that hard lenses are always below Tg; and soft are never below Tg. Also, the surface modification contains no oxygen (which is specifically omitted). The

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gas surface modification specifically mentions using gases that are incapable of polymerization; only crosslinking of the bulk polymer. The polymers and surface modifications mentioned are not heat stable; they will not withstand autoclaving (they will distort and melt). The patent '208 Patent also specifically uses acrylates., and with this type of chemistry, one does not have to worry about backbone polymer rotation. See, L. Winterton Declaration.

U. S. Patent No. 5,391,589 (" ' 589 Patent) discloses grafting surfaces onto lenses; and specifically hard lenses. In fact, this patent is very specific to hard contact lenses and surface graft-polymerization processes; Column 1, line 10-15. In the '589 Patent, a "special holder" was built to aid in the ultrasonic polymerization process for hard lenses. This process is also a four-step process for the surface modification in a de-oxygenated environment; see Column 3, line 24-35. The chemistry is acrylate esters, which is inapplicable to the present invention.

Based upon the description of the above secondary references, each of the references is very specific to a specific material, and one or ordinary skill in the art would not be motivated to use such techniques for surface treatment of the present invention. As generally described in Dr. L. Winterton's declaration, each would fail in use due to very nature of the claimed invention.

Clearly, there is no motivation in the secondary references that it would be desirable for one of ordinary skill in the art to improve any lens of the primary references by the surface treatment methods of Hofer, Lin, Sugiyama, or Kiguchi.

II. The Cancellation of Claim 1 Obviates the Double Patenting Rejection.

In the Office Action, the Examiner rejected Claim 1 for the following reasons:

Claim 1 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-10 of prior U.S. Patent No. 5,965,631. This is a double patenting rejection.

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Claim 1 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-64 of prior U.S. Patent No. 5,760,100. This is a double patenting rejection.

P. 3, Office Action. By Amendment, Applicants have cancelled Claim 1, and thus obviated the double patenting rejection.

III. Applicants have Added New Claims 183 to 242 in Order to More Fully Claim Their Invention.

As set forth the numerous IDS statements earlier filed in the present case, four issued patents flowing from the parent application of this application are now involved in litigation in the U.S. District Court in Georgia. Accordingly, in order to more fully claim their invention, applicants have added claims 183 to 242, which claims define over the cited prior art for the same reasons as set forth above. Specifically, Claims 183 to 218 , set forth novel elements of the invention in requiring that the subject hydogel lens have a defined period of continuous wear without substantial corneal swelling and "without having substantial amounts of lipid adsorption." Claims 219 to 242 are the same as original claims 159 to 182 in parent U.S. Patent Application 09/262,542, which were allowed in the parent case of this application. Generally, among other limitations, these claims require a "continous pathway" for oxygen transmission.

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IV. Request for Reconsideration and A Notice of Allowance.

For the above reasons, Applicants request reconsideration of the above rejections, and issuance of a Notice of Allowance. To the extent a further interview will clarify any issues now before the Examiner, the Applicant will be pleased to confer with the Examiner. It is requested that an interview be conducted with the Examiner prior to any issuance of the Final Office Action.

Respectfully submitted,

McDERMOTT, WILL & EMERY

Dated: January 7, 2002

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Appendix

Specification:

A mark up of the subsitute paragraph at Page 1, lines 3-5 is a follows:

This application is a continuation of Serial No. 09/262,542, filed on March 4, 1999, which is a continuation of Serial No. 09/108,714, filed July 1, 1998, which is a divisional of application Ser. No. 08/682,452, filed July 16, 1996, which is a divisional of application Ser. No. 08/569,816, filed December 8, 1995, which is a continuation-in-part of U.S. Application No. 08/301,166, filed on September 6, 1994. Priority is also claimed 119 for German Application No. 95810221.2 filed on April 4, 1995 and Swiss Application No. 1496/95 filed on May 19, 1995.

A mark up of the replacement paragraph at Page 16, line 35 to Page 17, line 4 is as follows.

An Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm^2/min [6.4×10^{-6} mm^2/min] is preferred for achieving sufficient on-eye movement. More preferably, the Ionoflux Diffusion Coefficient is greater than about 2.6×10^{-6} mm^2/min, while most preferably, the Ionoflux Diffusion Coefficient is greater than about 6.4×10^{-6} mm^2/min [1.5×10^{-6} mm^2/min]. It must be emphasized that the Ionoflux Diffusion Coefficient correlates with ion permeability through the lens, and thereby is a predictor of on-eye movement.

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